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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,566	01/29/2004	Donald Lee Morrow	P06308US01 - PHI 1365	5095
27142	7590	10/17/2005	EXAMINER	
MCKEE, VOORHEES & SEASE, P.L.C. ATTN: PIONEER HI-BRED 801 GRAND AVENUE, SUITE 3200 DES MOINES, IA 50309-2721			KRUSE, DAVID H	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/767,566

Applicant(s)

MORROW, DONALD LEE

Examiner

David H. Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005 and 08 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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STATUS OF THE APPLICATION

1. This Office action is in response to the Amendments filed on 13 June 2005 and 8 August 2005 and the Remarks filed on 13 June 2005.
2. The terminal disclaimer filed on 13 June 2005 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of U. S. Patent 6,727,413 has been reviewed and is accepted. The terminal disclaimer has been recorded.
3. The provisional rejection under 101 Double Patenting of claims 5 and 6 is withdrawn in view of Applicant's arguments.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. § 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. § 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. § 101.

6. Claim 11 is rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 2 and 11 of prior U.S. Patent No. 6,727,413. This is a double patenting rejection.

Claim Rejections - 35 USC § 112

7. Claims 25-30 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is indefinite because claim 11, upon which claim 25 depends, is directed to a plant having all of the morphological and physiological characteristics of inbred maize line PH5DR, not to inbred maize line PH5DR, hence the product of step (d) is not "derived from the inbred line PH5DR". Claims 26, 27 and 30 are similarly indefinite because of this discrepancy in the claims. Hence, the metes and bounds of the claimed invention are unclear.

Claims 28 and 29 are indefinite because it is unclear how the maize plant of claim 11 is employed in a plant breeding technique, since a plant breeding technique can "employ" a myriad of steps it is unclear where in such techniques the maize plant of claim 11 is actually employed, hence the metes and bounds of the claims are unclear.

8. Claims 1-10 remain rejected and claims 11-30 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 14 March 2005. Applicant's arguments filed 13 June 2005 have been fully considered but they are not persuasive.

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New claims 13-16, 18, 19 and 21-29 are directed to progeny of inbred maize line PH5DR and methods of using progeny of inbred maize line PH5DR.

Applicant only describes one F1 progeny of inbred maize line PH5DR in Table 4 produced by crossing with inbred maize line PH6KW. Applicant describes methods of introducing single gene traits into maize lines by crossing with another maize line having a single gene trait of interest or by introducing a transgene (page 21 of the specification).

Applicant does not describe the genus of progeny maize plants encompassed by the instant claims, nor does Applicant describe maize line PH5DR as having a genome comprising a single locus conversion.

Applicant argues that the genus of F1 hybrids encompassed by Applicant's claims 1-10 are described in relation to the cells and/or chromosomes of inbred line PH5DR, which provide an identifying structural feature possessed by all members of the claimed genus (page 6, 1st paragraph of the Remarks). This argument is not found to be persuasive because the genus of F1 hybrids would only be described by a partial structure, such a partial structure does not describe the function because such function would also depend upon the chromosomes of the "other" inbred line. See *In re Wallach*, 71 USPQ2d 1939 (CA FC 2004), at 1940: Claims in application directed to isolated DNA molecules encoding proteins that inhibit cytotoxic effects of tumor necrosis factor were properly rejected for failure to satisfy written description requirement of 35 U.S.C. § 112, since applicants claimed nucleic acids encoding protein for which they provided only partial sequence, and without approximately 95 percent of amino acid sequence that applicants did not disclose, it cannot be held that DNA molecules claimed in application

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have been described, since applicants' contention that they were in physical possession of protein does not establish their knowledge of that protein's amino acid sequence or any of its other descriptive properties, even though amino acid sequence is inherent property of protein, and since application does not provide adequate functional description, in that, with only partial amino acid sequence disclosed, chemical structure of nucleic acid molecules that can serve function of encoding protein's amino acid sequence cannot be determined.

Applicant argues that the genus of F1 hybrid seed and plants encompassed by Applicant's claims 1-10 all share the common structural attribute of having a complete set of the unique chromosomes of PH5DR and that it can be said that an F1 hybrid made with PH5DR comprises the unique chromosomes of inbred PH5DR (page 6, 3rd paragraph of the Remarks). This argument is not found to be persuasive because of the reasons given supra. The F1 hybrid structure only comprises half of the PH5DR chromosomes. It is the total genetic structure of the F1 hybrid that determines the function of the genome. The instant application does not lay open the actual DNA structure of inbred maize line PH5DR.

Applicant argues that the specification has provided guidance as to identifying characteristics of the genetic composition of the entire genus of hybrids claimed (page 6, 5th paragraph of the Remarks). This argument is not found to be persuasive because merely describing a method of identifying a genetic composition does not provide an adequate written description of the structure. See *Amgen inc. v Chagai Pharmaceutical co.*, 18 USPQ 2d 1016 (Fed. Cir. 1991), which teaches that the

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conception of a chemical compound requires the inventor to be able to define the compound so as to distinguish it from other materials, and to describe how to obtain it rather than simply defining it solely by its principle biological property; thus, when an inventor of a gene, which is a chemical compound albeit a complex one, is unable to envision detailed constitution of the gene so as to distinguish it from other materials, as well as a method of obtaining it, the conception is not achieved until a reduction to practice has occurred, and until after the gene has been isolated.

Applicant argues that according to *Enzo Biochem, Inc*, 296 F.3d at 1325, 63 U.S.P.Q.2d at 1613 the deposit of a material in a public depository is an adequate description of that material for purposes of the written description requirement (page 7, 1st paragraph of the Remarks). This argument is not found to be persuasive because the deposit in the instant application only describes inbred maize line PH5DR, not all F1 progeny produced therefrom.

Applicant argues that *Regents of University of California*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406, teaches that claims may satisfy the written description requirement where they disclose "structural features commonly possessed by members of the genus that distinguish them from others" and that the unique set of chromosomes of inbred maize line PH5DR is an identifying structural characteristic present in Applicant's seed deposit of PH5DR (page 7, 1st paragraph of the Remarks). This argument is not found to be persuasive because Applicant has only described by way of a deposit of biological material half of the genetic structure. The genus of F1 progeny will by their nature have widely variant functional features that are not common to inbred maize line PH5DR.

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While a description of a representative number of species is adequate to represent an entire genus, wherein there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus (see MPEP 2163).

Applicant argues that the section of Kevern ('009 column 4, lines 41-46) is specifically discussing segregating populations of seed, and that a segregating population is not the invention claimed in claims 1-10 (page 7, 3rd paragraph of the Remarks). Applicant argues that F1 hybrid seed will inherit the stable genetics of the inbred line used to produce it, which genetics will be present in both the inbred and the F1 hybrid and that the use of stable inbred lines, such as PH5DR, does allow for one of ordinary skill in the art to make F1 hybrids produced from inbred line PH5DR (page 8, 1st paragraph of the Remarks). These arguments are not found to be persuasive because, although Kevern is referring to F2 segregating populations at column 4, lines 47-50, Kevern states that typically neither the genotypes of the breeding cross parents nor the desired genotype to be selected is known in detail and that it is not known how the desired genotype would react to the environment (lines 51-54). This statement by Kevern applies not only to F2 progeny but also to F1 progeny. Table 4 of the instant application is directed to an F1 hybrid produced by crossing inbred PH5DR with PH6KW, a single species of the claimed genus. The single species described in Table 4 does not adequately describe the genus encompassed by the instant claims because each second inbred parent would produce a different and distinct F1 hybrid progeny. Applicant only describes, by way of a deposit of inbred PH5DR, a partial structure of the claimed genus of F1 hybrid maize plants.

Applicant argues in reference to Table 3 of the instant application, inbred lines PH5DR and PH3DT were crossed to a large number of common inbreds (ones that were not PH5DR and PH3DT, respectively) and the results of these crosses were evaluated and reported in said table. Applicant also argues that Table 3 demonstrates that PH5DR, at the time of the application was filed, had been crossed to different inbred lines in order to produce different F1 hybrid varieties (page 8, 3rd and 4th paragraphs of the Remarks). These arguments are not found to be persuasive because Table 3 does not describe the individual species, only a summary of traits. It is unclear if Table 3 adequately describes the variation within the genus of F1 progeny claimed as addressed supra.

Applicant argues that according to the MPEP, § 2163(II)(A)(3)(a)(ii), the written description requirement for a genus may be satisfied by sufficiently describing a representative number of species actually reduced to practice (page 9, 2nd paragraph of the Remarks). This argument is not found to be persuasive because while a description of a representative number of species is adequate to represent an entire genus, wherein there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus (see MPEP § 2163).

As directed to new claims 13-16, 18, 19 and 21-29, the invention of said claims lack adequate written description because they are directed to progeny of inbred maize line PH5DR and methods of using said progeny. In addition, claims 19, 21 and 22-24 are directed to inbred maize plants having a single locus conversion or gene that Applicant does not describe inbred maize line PH5DR as inherently having. Claims 19-

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22 are directed to inbred maize line PH5DR comprising a single locus, wherein Applicant does not describe a single species of such an inbred maize line, the Examiner notes that a "locus" can comprise multiple coding sequences due to linkage drag. A "locus" is defined in the art as a position occupied by a gene on a chromosome. The instant application refers to a "single gene conversion or introgression" at page 21.

Claims 11-30 are rejected for introduction of New Matter into the claims. At claim 11, the specification does not provide written description support for a maize plant having all the morphological and physiological characteristics of inbred maize line PH5DR, hence all claims dependent thereupon also comprise New Matter. At claims 19-22, the specification does not provide written description support for "a single locus conversion" because the specification only describes "a single gene conversion" at page 21.

9. Claims 1-10 remain rejected and claims 13-16 and 18-29 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 14 March 2005. Applicant's arguments filed 13 June 2005 have been fully considered but they are not persuasive.

Applicant argues in reference to Kevern that a segregating population is not the invention claimed in claims 1-10, an F1 hybrid of the claimed invention is not a

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segregating population as assumed by the Examiner rather, the F1 hybrids of the present application are based on stable inbred lines where the genetics are of a fixed nature and whereby the hybrid receives the genetics of the inbred line PH5DR, as may be further exemplified by the SSR profile. Applicant also argues that an F1 hybrid seed will inherit the stable genetics of the inbred line used to produce it, which genetics will be present in both the inbred and the F1 hybrid (page 10, 3rd paragraph of the Remarks). This argument is not found to be persuasive and is extensively addressed supra. Applicant states that a single cross maize hybrid results from the cross of two inbred line, each of which has a genotype that "complements the genotype" of the other (page 4, lines 28-29 of the specification). Applicant does not teach one of skill in the art what "other" inbred lines would complement the genotype of inbred maize line PH5DR, Applicant merely invites experimentation by one of skill in the art to produce a myriad of F1 progeny to determine what "other" inbred maize lines would "complement" the genotype of inbred maize line PH5DR. Such trial and error experimentation by one of skill in the art would have been undue because of the vast number of "other" inbred maize lines available.

Applicant argues that Carlone is specifically discussing selection within the segregating populations of seed that a breeder uses for inbred development, that an F1 hybrid of the claimed invention is not a segregating population as assumed by the Examiner, and further, the patent cited by the Examiner is one in which Carlone developed a novel inbred line and sought and was allowed claims to the hybrid seed and plants produced from the novel inbred line (page 11, 2nd paragraph of the

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Remarks). First, each application is examiner upon it's own merits and what was allowed in another is irrelevant to the instant rejection. Second, the instant claims require the use, by one of skill in the art, of a second inbred parent maize plant. The teachings of Carlone is relevant to the instant rejection because it teaches that one of skill in the art would have to practice undue trial and error experimentation to cross the exemplified PH5DR inbred maize line with a myriad of other inbred maize lines to make useful F1 hybrids as broadly claimed.

Applicants argue that Segebart is discussing segregating F2 populations of seed, in contrast, the claimed invention teaches the use of stable and genetically fixed inbred lines to produce an F1 hybrid. Applicants argue that the claimed F1 hybrids are not from a segregating population but rather from a highly homogeneous, homozygous and reproducible inbred maize line PH5DR, and that an F1 hybrid is not the result of a segregating population but rather is the result of a superior, stable and genetically fixed inbred maize line that produces the claimed F1 hybrids (paragraph spanning pages 11-12 of the Remarks and page 12 of the Remarks). These arguments are not found to be persuasive because Applicant teaches only one inbred parent of the claimed F1 hybrid maize plants. Applicant does not teach what number or combination of genes controlling useful characteristics of a maize plant are in inbred maize plant PH5DR. Segebart teaches that no line contains the favorable allele at all loci, and that different alleles have different economic values depending on the genetic background and field environment in which the hybrid is grown. Segebart also teaches that there are many genes affecting grain yield and that each of these has a relatively small effect on this

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trait. The fact that Segebart is discussing the development of inbred maize lines from segregating F2 populations does not obviate the teachings that one of skill in the art must practice undue trial and error experimentation in combining two inbred maize plants to determine what combination is useful. Given the breadth of the instant claims, it remains the Examiner's opinion that it would have required undue trial and error experimentation of make and use the genus of F1 hybrid progeny of inbred maize line PH5DR as broadly claimed.

Applicant argues that one of ordinary skill in the art would know that the pericarp tissue of inbred PH5DR is genetically identical to the maternal parent and that it is well known to one of skill in the art that a maize seed is comprised of various types of tissue with different genetic composition. Applicant further argues that intact cells from inbred PH5DR will be a component of the F1 hybrid seed produced with PH5DR as the maternal parent and that the genetic composition of the pericarp tissue of the F1 hybrid seed is an identifying structural feature present in the plants produced from the deposited seed of PH5DR and can be characterized by molecular markers (paragraph spanning pages 12-13 of the Remarks). These arguments are not found to be persuasive because the "use" of the F1 progeny maize plant does not lie in the pericarp tissue, but in the embryonic tissue of the seed that produces said F1 progeny plant. In addition, the pericarp tissue of inbred PH5DR would only be present if inbred PH5DR were the female parent plant.

New claims 13-16 and 18-29 are lack adequate enablement. Claims 13-16 and 18 lack enablement for the reasons given supra. Claims 19-22 directed to a single gene

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conversion lack adequate enablement because the inbred maize line PH5DR is not taught to have such a single gene conversion (claims 19, 21 and 22), and the transformed maize plant of claim 20 encompasses undefined "single locus" inserts wherein it is unclear what function the "locus" actually has, thus how one of ordinary skill in the art would use the myriad of transformed maize plant. At claim 23, the maize line PH5DR is not taught as having a gene conferring male sterility or a transgene conferring the traits listed in claim 24. Claims 25-29 lack adequate enablement for the reasons given supra, Applicant does not teach one of skill in the art what "other" inbred lines would complement the genotype of inbred maize line PH5DR, Applicant merely invites experimentation by one of skill in the art to produce a myriad of progeny to determine what "other" inbred maize lines would "complement" the genotype of inbred maize line PH5DR. Such trial and error experimentation by one of skill in the art would have been undue because of the vast number of "other" inbred maize lines available.

Response to Arguments

10. Applicant's arguments filed 8 August 2005 have been fully considered but they are not persuasive. The applicability of the non-precedential reasoning of the Board of Appeals and Interferences in another Applicant's applications is not proper.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. No claims are allowed.

13. The claims are free of the prior art, which neither teaches nor suggests inbred maize line PH5DR or methods of using same.

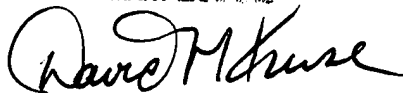
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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (571) 272-0745. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



David H. Kruse, Ph.D.
13 October 2005

15. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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